

### **Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of the claims in the application:

#### **Listing of Claims:**

1. (Cancelled)

Claims 2- 36 (Cancelled).

37. (New) An electronic device for outputting a signal configured according to at least one control parameter of a patient, comprising:

(a) an electronic data receiver configured for receiving a prior disease control parameter value  $X(t_i)$ ;

(b) a memory for storing optimal control parameter values  $R(t_i)$  and  $R(t_j)$ , self-care values  $S_{M(ii)}$  of a patient, optimal self-care values  $O_{M(ii)}$ , and one or more scaling factors  $K_M$ ;

(c) a microprocessor, in communication with said electronic data receiver and said memory, for calculating a further value for enabling corrective action to be performed to prevent hypoglycemia or hyperglycemia, said further value being based on said self-care values  $S_{M(ii)}$  and  $O_{M(ii)}$ , said control parameter values  $X(t_i)$ ,  $R(t_i)$  and  $R(t_j)$ , and said scaling factors  $K_M$ ; and

(d) an output port for outputting a signal configured according to said further value, thereby enabling said corrective action to be performed to prevent said hypoglycemia or hyperglycemia.

38. (New) The device of claim 37, further comprising a housing, wherein said memory and said microprocessor are housed within said housing and said output port is integral with said housing to provide a hand-held, readily transportable device.

39. (New) The device of claim 38, wherein said electronic data receiver is arranged within said housing.

40. (New) An apparatus for assisting a patient having diabetes mellitus in controlling blood glucose, said apparatus comprising:

(a) an electronic data receiver for receiving a blood glucose value  $G(t_d)$  representative of a blood glucose concentration of the patient at time  $t_d$ ;

(b) a memory for storing an insulin sensitivity value representative of an insulin sensitivity of the patient, an insulin dose value  $I_k$  representative of an insulin dose administered to the patient prior to time  $t_d$ , and information for determining an insulin action value  $F_k(t_d)$  representative of a fraction of insulin action remaining at time  $t_d$  from said insulin dose;

(c) a processor connected to said electronic data receiver and said memory for determining said insulin action value  $F_k(t_d)$  and for determining a further value for enabling a corrective action to prevent hypoglycemia or hyperglycemia, wherein said processor determines said further value in dependence upon said blood glucose value  $G(t_d)$ , said insulin dose value  $I_k$ , said insulin sensitivity value, and said insulin action value  $F_k(t_d)$ ;

(d) an interpolation formula to calculate the insulin action value  $F_k(t_d)$  programmed into the processor;

(e) a formula to calculate the further value programmed into the processor; and  
(f) an output port coupled with said processor for outputting a signal configured according to said further value, thereby enabling corrective action to be performed to prevent hypoglycemia or hyperglycemia based on said signal.

41. (New) The apparatus of claim 40, wherein the formula to calculate the insulin action value comprises:

$$F_k(t_d) = Y_0 + ((Z_k - X_0)(Y_1 - Y_0)/(X_1 - X_0)),$$

wherein  $X_0$  represents an initial insulin dose,  $Y_0$  represents an insulin action value at initial dose  $X_0$ ,  $X_1$  represents a following insulin dose,  $Y_1$  represents an insulin action value at following insulin dose  $X_1$ , and  $Z_k$  represents time after injection of insulin dose  $I_k$  at time  $t_d$ .

42. (New) The apparatus of claim 40, wherein the formula to calculate the further value is based in part upon a future glucose value calculation according to:

$$G(t_j) = G(t_d) - S \bullet \sum_k [I_k F_k(t_d) - F_k(t_j)]$$

wherein  $S$  represents insulin sensitivity value,  $I_k$  represents insulin dose values administered prior to time  $t_d$ , and  $F_k(t_j)$  represents insulin action values at time  $(t_j)$ ,  $k=1$  represents a single insulin bolus dose and a supplemental insulin bolus dose, and  $N$  represents the total number of insulin bolus doses and supplemental insulin bolus doses.

43. (New) The apparatus of claim 42, wherein said memory stores maximum and minimum values defining a target blood glucose range of the patient, said processor further for determining if said future blood glucose value  $G(t_j)$  lies outside of said target range and for determining said corrective action for the patient when said future blood glucose value  $G(t_j)$  lies outside of said target range, and said output port for outputting said signal according to said determined corrective action.

44. (New) The apparatus of claim 40, wherein said memory further for storing a target blood glucose value of the patient, said corrective action comprises an administration of a supplemental insulin dose, and said processor further for determining said supplemental insulin dose in dependence in part upon said insulin sensitivity value.

45. (New) The apparatus of claim 40, wherein said memory further for storing a target blood glucose value of the patient, said corrective action comprises a consumption of a number of grams of carbohydrates, and said processor further for determining said number of grams.

46. (New) The apparatus of claim 40, wherein said electronic data receiver comprises a blood glucose monitor for measuring a blood sample of the patient and for producing said blood glucose value  $G(t_d)$  from a measurement of said blood sample.

47. (New) The apparatus of claim 40, wherein said insulin dose has an insulin type, said electronic data receiver for receiving said insulin type, and said processor for determining

said insulin action value  $F_k(t_d)$  in dependence upon said insulin type.

48. (New) The apparatus of claim 47, wherein said insulin type includes regular insulin or lispro insulin or a combination thereof.

49. (New) The apparatus of claim 40, wherein said processor for determining an insulin action value  $F_k(t_j)$  representative of a fraction of insulin action remaining at time  $t_j$  from said insulin dose and for determining said further value in further dependence upon said insulin action value  $F_k(t_j)$ .

50. (New) The apparatus of claim 49, wherein said processor for determining an ultimate time point at which said insulin dose will have no insulin action remaining and for setting time  $t_j$  equal to said ultimate time point.

51. (New) The apparatus of claim 40, wherein said processor for determining a plurality of future blood glucose values representative of a corresponding plurality of expected blood glucose concentrations of the patient.

52. (New) The apparatus of claim 40, further comprising a further output port coupled to said processor for establishing a communication link between said apparatus and a healthcare provider computer and for transmitting and receiving data therebetween.

53. (New) The apparatus of claim 52, wherein said further output port comprises a modem for establishing said communication link through a communication network.

54. (New) The apparatus of claim 52, wherein said further output port comprises an input/ output port for establishing said communication link through a connection cord.

55. (New) A system for assisting a patient having diabetes mellitus in controlling blood glucose, said system comprising:

- (a) an electronic data receiver for receiving a blood glucose value  $G(t_d)$  representative of a blood glucose concentration of the patient at time  $t_d$ ;
- (b) a memory for storing maximum and minimum values defining a target blood glucose range of the patient, an insulin sensitivity value representative of an insulin sensitivity of the patient, an insulin dose value representative of an insulin dose administered to the patient prior to time  $t_d$ , and information for determining an insulin action value  $F_k(t_d)$  representative of a fraction of insulin action remaining at time  $t_d$  from said insulin dose;
- (c) a processor connected to said electronic data receiver and said memory for determining said insulin action value  $F_k(t_d)$ , for determining a further value enabling a corrective action to be performed to prevent hypoglycemia or hyperglycemia at a later time  $t_j$ , and for determining a corrective action for the patient when said further value indicates that a future blood glucose value of the patient will fall outside said target range without said corrective action, wherein said processor determines said further value in dependence upon said blood glucose value  $G(t_d)$ , said insulin dose value, said insulin sensitivity value, and said insulin action value  $F_k(t_d)$ ; and
- (d) a display connected to said processor for recommending said corrective action to the patient.

56. (New) The system of claim 55, wherein said memory further stores a hypoglycemic value indicative of a hypoglycemic threshold of the patient, said processor determines if said further value indicates that a future blood glucose value will lie below said hypoglycemic value, and said system further comprises an audio output connected to said processor for audibly alerting the patient when said further value indicates that a future blood glucose value will lie below said hypoglycemic value.

57. (New) The system of claim 55, wherein said input means comprises a blood glucose measuring means for measuring a blood sample of the patient and for producing said blood glucose value  $G(t_d)$  from a measurement of said blood sample.

58. (New) The system of claim 55, wherein said insulin dose has an insulin type, said electronic data receiver receiving data corresponding to said insulin type, and said processor for determining said insulin action value  $F_k(t_d)$  in dependence upon said insulin type.

59. (New) The system of claim 58, wherein said insulin type comprises regular insulin or lispro insulin, or a combination thereof.

60. (New) The system of claim 55, wherein said processor for determining an insulin action value  $F_k(t_j)$  representative of a fraction of insulin action that would be remaining at a future time  $t_j$  from said insulin dose and for determining a future blood glucose value  $G(t_j)$  in dependence upon said further value and said insulin action value  $F_k(t_j)$ .

61. (New) The system of claim 60, wherein said processor for determining an ultimate time point at which said insulin dose will have no insulin action remaining and for setting time  $t_j$  equal to said ultimate time point.

62. (New) The system of claim 55, wherein said processor for determining a plurality of future blood glucose values representative of a corresponding plurality of expected blood glucose concentrations of the patient, and wherein said display means includes means for displaying said future blood glucose values in graphical form.

63. (New) The system of claim 55, wherein said electronic data receiver for receiving a plurality of blood glucose values and a plurality of insulin dose values, and said system further comprises a computer in communication with said processor for receiving said blood glucose values and said insulin dose values and for calculating from said blood glucose values and said insulin dose values an adjusted insulin sensitivity value.

64. (New) The system of claim 63, wherein said electronic data receiver, said memory, said processor, and said display are included in a patient-operated apparatus, said computer comprises a healthcare provider computer, and said apparatus includes a communication means connected to said processor for establishing a communication link between said apparatus and said healthcare provider computer.

65. (New) The system of claim 64, wherein said communication means comprises a modem for establishing said communication link through a communication network.

66. (New) The system of claim 64, wherein said communication means comprises an input/output port for establishing said communication link through a connection cord.